DETAILED ACTION

Claims 1-19 are pending.

It is noted that the last line of newly added claim 19 appears on the remarks page of the response. The claims should be filed as a completely separate document. In the interest of compact prosecution the amendment will be entered and considered.

Election/Restrictions

It is noted that claim 14 was originally drawn as a use claim and was interpreted as a product (emulsifier; Group II), method of making the product (Group I) and a method of using the emulsifier to make products in the food sector (Group III). Claim 14 has been amended as a product claim, which is deemed as belonging only to restriction Group II. On 2/11/2011, Examiner Hanley confirmed with Jennifer Branigan that the method of making an emulsifier (claims 1-13 and 16-19) was elected.

Applicant's election with traverse of Group I, claims 1-14 and new claims 16-19, drawn to a method as in the reply filed on 12/3/2010 is acknowledged. The traversal is on the ground(s) that there is no undue search burden. This is not found persuasive because the instant application is a national stage entry of PCT and is therefore subject to lack of unity requirement. Search burden is not a requirement for a showing of lack of unity. Lack of unity is demonstrated when it is shown that the invention does not make a contribution over the prior art. This was demonstrated with the citation of US 2002/0020157. Although claim 14 is now drawn to an emulsion made by the process of claim 1, the disclosure of US 2002/0020157 meets the limitations of the amended claim, now deemed as Group II. The method of claim 1 produces a mixture of

lysophospholipids, monoglycerides, and diglycerides. '157 discloses an emulsion comprising lysophospholipids, monoglycerides, diglycerides, phospholipids, glycolipids and lysoglycolipids. The transitional language of claim 14 is "comprising". "Comprising" is open language. Thus, the prior art composition can contain additional elements that are encompassed by, but not specifically named, by the claims.

The requirement is still deemed proper and is therefore made FINAL.

Claims 14 and 15 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 12/3/2010.

Claims 1-13 and 16-19 are presented for examination.

Specification

The abstract of the disclosure is objected to because it is too long. The abstract should be no longer than 150 words. Correction is required. See MPEP § 608.01(b).

Claim Suggestions

In claim 13, at line 3, it is suggested that the ratio of components be expressed as “1:0.25 to 1:4.0”

Since newly added claims 16-19 are dependent claims, it is suggested that they begin with the word "The" instead of "A".

In claims 17, it is suggested that line 2 be changed to “from *Candida* or *Aspergillus*.”

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-13 and 16-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is rejected because the difference in the breadth of the parts of the claims are confusing. Part (a) is drawn to charging a mixture of a phospholipid component and a triacylglyceride component. A phospholipid component can be the parts that make up the phospholipid (e.g., phosphate). Likewise, a triglyceride component can be the part of the molecule that makes up the triglyceride (e.g., glycerol). The breadth of these limitations conflicts with the reaction with the lipase since lipases react with phospholipid molecules and triglyceride molecules and not the parts (e.g., components) that make up the molecules.

Claim 1 is rejected because it is unclear if “the mixture” in the third line of part (b) refers to the mixture in part (a) or a mixture that results from step (b).

Claim 1 is rejected because it is unclear to which mixture in the previous parts of the claim “the mixture” in step (d) refers.

Claims 1 and 8 are rejected because the term "(phospho)lipase" is vague and indefinite. It is unclear if the term in parentheses is a limitation for the entire term. That is, does the term mean a phospholipase, a lipase or a lipase having a phosphoryl component or something else?

Claims 3 and 4 are rejected because it is unclear what the basis of “by weight” is. That is, are the percentages of the phospholipid component and the triglyceride components based on the individual weights of these components or the weight of the charged mixture in claim 1(a) or the total weight of the charged mixture plus the aqueous solution or just the weight of the charged components?

Claim 7 is rejected because in the phrase "the lipase and/or phospholipase", the concept of a lipase and a phospholipase lacks antecedent basis in the term "(phospho)lipase" in claim 1. The possible meanings of “(phospho)lipase” are interpreted to be in the alternative.

Claim 8 is rejected because it is unclear what the basis for the concentration of "mg/ml" is. Is it based on the volume of the entire mixture for the reaction or the volume of the aqueous solution of the enzyme which is added to the charged mixture?

Claim 12 is rejected because it is unclear if the percentages of the products are based on each fraction or the total of the mixture of product obtained from the reaction.

Claims 2, 5, 6, 9-11, 13 and 16-19 are rejected because they are dependent claims that do not overcome the deficiencies of the rejected claims from which they depend.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-10, 12, 13, 16 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yoshitomi et al. (JP 63302929) in view of Tweddell et al. (1997).

Yoshitomi et al. disclose the preparation of an emulsifier comprising treating a mixture of phospholipid and oils/fat with phospholipase A and a lipase (instant claims 1 and 7, both in part). Yoshitomi et al. disclose that lecithins (instant claims 1, in part, and 2) are commonly mixtures of phospholipid and triglycerides (oils/fats) and they are equivalent to “mixtures of phospholipid and oils/fats”. The ordinary artisan would reasonably interpret this disclosure to mean that lecithin sources comprises oils that have triglycerides, thus meeting the limitations of claims 1 (in part) and 3, in part (oil is disclosed). Common sources of lecithins are from soybean (instant claim 16), rapeseed, safflower etc. (p. 4 of the translation, first two paragraphs). Since the lecithin is from vegetable the ordinary artisan would reasonably conclude that the oil contained therein is also from the same source, a vegetable (instant claim 3).

Yoshitomi et al. generically teach that a mixture of phospholipid and oils/fats are dispersed in water to make a suspension and the pH is optimized with NaOH. Lipase and phospholipase are added and the upper limit of the temperature is 50 degrees C. The reaction time is about 2 to 10 hours. After the reaction, the product is obtained by drying (p. 4-5 of the translation, joining paragraph).

In a specific example, 20 g of lecithin DX, interpreted to contain the oil and lecithin) was dispersed in 180 g of warm water (instant claim 1(a)) and homogenized. The pH was adjusted and phospholipase and lipase (20 mg and 2 mg, respectively) were added (instant claim 1(b)). The reaction was carried out at 50 degrees C (instant claim 1(c)). After 8 hours the reaction was terminated by the addition of acid and concentrated and dried (instant claim 1(d); p. 6-7, translation). The disclosure of 50 degrees C for the reaction temperature is a specie that anticipates the claimed ranges of between 20 to 80 degrees C (instant claim 1(c)), of between 35 to 60 degrees C (instant claim 6) and of between 40 to 50 degrees C (instant claim 9). In instant claim 9, between 40 and 50 degrees C is interpreted to include the endpoints of the range. Alternatively, if the limitation of “between 40 and 50 degrees C” does not include the endpoints of the range, the ordinary artisan would be motivated to optimize the temperature around the endpoints of the ranges to obtain the optimal temperature of the reaction to produce the most product.

The disclosure of a time period of 8 hours is a specie that anticipates the claimed ranges of at least 2 hours (instant claim 1(c)), between 5 and 20 hours (instant claim 10) and between 8 to 12 hours (instant claim 19). In instant claim 19, between 8 and 12

hours is interpreted to include the endpoints of the range. Alternatively, if the limitation of "between 8 and 12 hours" does not include the endpoints of the range, the ordinary artisan would be motivated to optimize the time of the reaction around the endpoints of the ranges to obtain the optimal reaction time to produce the most product.

Yoshitomi et al. do not disclose that the content of water in the mixture is between 3 and 15% by weight.

Tweddell et al. disclose the optimization of a reaction medium for an esterification reaction catalyzed by a microbial lipase. It is disclosed that biphasic systems were formed by adding lipase dissolved in water to hexane or hexane containing surfactants. The reaction was carried out in the biphasic system with the reactants oleic acid and ethanol with various amounts of water to form a biphasic reaction medium (p. 940, left col. first two full paragraphs). Different concentrations of water in each system were tested. The tested systems contain 10%, 20%, 30%, 40%, 60%, 80% of water or 100% water (e.g., no hexane/surfactant; not a biphasic system). Tweddell et al. disclose that the lowest rate of conversion was obtained in the totally aqueous system while the best rates of conversion were achieved for reaction systems with 10% or 20% water. Although Tweddell et al. disclose that 20% was the best water concentration, it is noted that the error bars for 10% and 20% are overlapping (joining paragraph, p. 940-941 and Fig. 1). As shown in Fig. 2, an increase in the proportion as water has a strong negative thermodynamic equilibrium on the reaction (p. 941, Fig. 2 and top of right col.). Thus, the ordinary artisan would reasonably conclude from the disclosure of Tweddell et al. that reactions involving hydrophobic substrates and a lipase catalyst are optimally

carried out in a biphasic system with low concentrations of water to achieve high product yields. 10% water content is a specie that anticipates the claimed range of between 3 and 15% (instant claim 1(c)). It is noted that the transitional language for the method is "comprising". "Comprising" is open language. Thus the prior art method can contain elements (e.g., hexane as part of the solvent) not specifically named by the claims.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to run the lipase/phospholipase-catalyzed reaction disclosed by Yoshitomi et al. in a biphasic solution comprising hexane. The ordinary artisan would have been motivated to do so because Tweddell et al. demonstrate that running a reaction comprising a hydrophobic substrate with a lipase catalyst in a biphasic system with a water content of 10% provides a higher product yield compared to the reaction run in pure water. The ordinary artisan would have had a reasoanble expectation the reaction disclosed by Yoshitomi et al. could be run in a biphasic system because the disclosed reaction contains hydrophobic elements (oil and lecithin) that can dissolve in hexane and Tweddell et al. demonstrates that the biphasic reaction system is successful for a lipase-catalyzed system.

The combined references are silent regarding the content and ratio of the products (instant claims 12 and 13, respectively) but meets the claimed limitations (e.g., the reaction of the combined references meets the claimed method steps) which indicates that the claimed characteristics should be present in the prior art invention as

also as those instantly claimed. In this case, burden is shifted to the Applicant to distinguish the instant invention over the prior art.

It is noted that In re Best (195 USPQ 430) and In re Fitzgerald (205 USPQ 594) discuss the support of rejections wherein the prior art discloses subject matter which there is reason to believe naturally includes functions that are newly cited or is identical to a product instantly claimed. In re Best and In re Fitzgerald are relevant to the instant method claims since it is the properties of the reactants in the reaction that determine the outcome of the reaction. In such a situation the burden is shifted to the applicants to "prove that subject matter shown to be in the prior art does not possess characteristic relied on" (205 USPQ 594, second column, first full paragraph).

While the references listed above do not specifically teach that the concentration of the enzyme is 0.05 to 10 mg/ml (instant claim 8) and the concentration of reactants (instant claims 4 and 5), one of ordinary skill in the art would recognize the concentration of the enzyme and reactants is a result effective variable dependant on the desired rate of the reaction and amount of product desired. This is motivation for someone of ordinary skill in the art to practice or test the parameter values widely to find those that are functional or optimal which then would be inclusive or cover that values as instantly claimed. Absent any teaching of criticality by the Applicant concerning the concentration of enzyme, it would be prima facie obvious that one of ordinary skill in the art would recognize these limitations are result effective variable which can be met as a matter of routine optimization (MPEP § 2144.

Therefore, the claimed invention would have been obvious to one of ordinary skill in the art at the time the invention as made because running a lipase-catalyzed reaction in a biphasic system with 10% water produces more the of desired product.

Claims 1-10, 12, 13, 16, 17 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yoshitomi et al. (JP 63302929) in view of Tweddell et al. (1997), as applied to claims 1-10, 12, 13, 16 and 19, in further view of Oester et al. (US 5,591,615) and Yagi et al. (JP 363042691; Derwent abstract).

The combined disclosures by Yoshitomi et al. and Tweddell et al. are discussed supra.

The combined disclosures do not disclose that the source of the lipase is from *Aspergillus* (instant claim 17).

Oester et al. disclose that lipase from *Aspergillus niger* splits the ester bonds of triglycerides (col. 1, lines 42-45).

Yagi et al. disclose that lipase belonging to the *Aspergillus* genus such as *Aspergillus niger* can hydrolyze lecithin to produce lyso-type phospholipids (abstract).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ a lipase from *Aspergillus niger* to serve as the lipase in the reaction of the combined disclosures to react with lecithin and oil. The ordinary artisan would have been motivated to do so because lipase from *Aspergillus niger* is capable of hydrolyzing lecithin and triglycerides to make the desired emulsifier product of the combined references. The ordinary artisan would have had a reasoanble

expectation that one could employ a lipase from *Aspergillus niger* to successfully hydrolyze lecithin and triglycerides as disclosed by the combined references since Oester et al. and Yagi et al. teach that lipases from *Aspergillus niger* are able to accomplish this.

Therefore, the claimed invention would have been obvious to one of ordinary skill in the art at the time the invention as made because lipase from *Aspergillus niger* has the desired enzymatic activities to hydrolyze lecithin and triglycerides.

Claims 1-13, 16, 18 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yoshitomi et al. (JP 63302929) in view of Tweddell et al. (1997), as applied to claims 1-10, 12, 13, 16 and 19, in further view of Muhlebach et al. (US 6,410,480) and Muller et al. (US 20040006096).

The combined disclosures by Yoshitomi et al. and Tweddell et al. are discussed supra.

The combined disclosures do not disclose that the drying takes place under a vacuum (instant claims18) or that the temperature during drying is between 60 and 80 degrees C.

Muhlebach et al. disclose the preparation of oxopyrazilines wherein after a reaction the product can be in the form of a filter cake which can be washed with water and hexane and then subsequently dried under reduced pressure (e.g., a vacuum) at a temperature of 60 degrees C over P_2O_5 (col. 48, lines 63-67).

Muller et al. disclose the preparation of substituted alkanohydroxamic acids wherein a reaction product can be washed with hexane and water and then dried in a vacuum at a temperature of 60 degrees C.

The disclosure of 60 degrees C is a specie that anticipates the claimed range of between 60 and 80 degrees. Between 60 and 80 degrees C is interpreted to include the endpoints of the range. Alternatively, if the endpoints are not part of the range, it would have been obvious to the ordinary artisan to optimize the temperature of drying around the endpoints to obtained the driest product possible.

Thus, from the disclosures by Muhlebach et al. and Muller et al., the ordinary artisan would reasonably conclude that water and hexane can be removed from a reaction product by the application of heat at 60 degrees C and under a vacuum.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to dry the emulsifier product made by the method of the combined references wherein the reaction is carried out in a biphasic medium comprising hexane and water by performing the drying step at a temperature of about 60 degrees C under vacuum. The ordinary artisan would have been motivated to do and would have had a reasoanble expectation of success of drying the product since the cited prior art teaches the accomplishment of removing water and hexane from reaction products by this method.

Therefore, the claimed invention would have been obvious to one of ordinary skill in the art at the time the invention as made because subjecting a product to a vacuum at 60 degrees C reasonably dries hexane and water from said product.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SUSAN HANLEY whose telephone number is (571)272-2508. The examiner can normally be reached on M-F 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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/Susan Hanley/
Examiner, Art Unit 1651